ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT LAND DIVISION HAZARDOUS WASTE PROGRAM ADMINISTRATIVE CODE

CHAPTER 335-14-7
STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

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335-14-7-.01 [Reserved].
Author:
Statutory Authority:
History:

335-14-7-.02 [Reserved].
Author:
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History:

335-14-7-.03 Recycled Materials Used In A Manner Constituting Disposal.

(1) Applicability.

(a) The requirements of 335-14-7-.03 apply to recyclable materials that are applied to or placed on the land:

1. Without mixing with any, other substance(s); or

2. After mixing or combining with any other substance(s). These materials will be referred to throughout 335-14-7-.03 as "materials used in a manner that constitutes disposal".

(b) Products produced for the general public's use that are used in a manner that constitutes disposal and that contain recyclable materials are not presently subject to regulation if the recyclable materials have undergone a chemical reaction in the course of producing the products so as to become inseparable by physical means and if such products meet the

applicable treatment standards in Rule 335-14-9-.04 (or applicable prohibition levels in 335-14-9-.03(13) or RCRA Section 3004(d), where no treatment standards have been established) for each recyclable material (i.e., hazardous waste) that they contain, and the recycler complies with CFR 268.7(b)(6).

(c) Anti-skid/deicing uses of slags, which are generated from high temperature metals recovery (HTMR) processing of hazardous waste K061, K062, and F006, in a manner constituting disposal are not covered by the exemption in 335-14-7-.03(1)(b) and remain subject to regulation.

(d) Fertilizers that contain recyclable materials are not subject to regulation provided that:

1. They are zinc fertilizers excluded from the definition of solid waste according to 335-14-2-.01(4)(a)20; or

(2) Standards applicable to generators and transporters of materials used in a manner that constitutes disposal. Generators and transporters of materials that are used in a manner that constitutes disposal are subject to the applicable requirements of Chapters 335-14-3 and 335-14-4.

(3) Standards applicable to storers of materials that are to be used in a manner that constitutes disposal who are not the ultimate users. Owners or operators of facilities that store recyclable materials that are to be used in a manner that constitutes disposal, but who are not the ultimate users of the materials, are regulated under all applicable provisions of Rules 335-14-5-.01 through 335-14-5-.12 and 335-14-6-.01 through 335-14-6-.12 and Chapter 335-14-8, and the notification requirement under 335-14-3-.01(8).

(4) Standards applicable to users of materials that are used in a manner that constitutes disposal.

(a) Owners or operators of facilities that use recyclable materials in a manner that constitutes disposal are regulated under all applicable provisions of Rules 335-14-5-.01 through 335-14-5-.14 and 335-14-6-.01 through 335-14-6-.14, Chapter 335-14-8 and Chapter 335-14-9, and the notification requirement under Section 3010 of RCRA. (These regulations do not apply to products which contain these recyclable materials under the provisions of 335-14-7-.03(1)(b).)

(b) The use of waste or used oil or other material, which is contaminated with dioxin or any other hazardous waste (other than a waste identified solely on the basis of ignitability), for dust suppression or road treatment is prohibited.

Author: Stephen C. Maurer; Edwin C. Johnston; Bradley N. Curvin; Vernon H. Crockett

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335-14-7-.04 [Reserved].
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335-14-7-.05 [Reserved].
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335-14-7-.06 Recyclable Materials Utilized For Precious Metal Recovery.

(1) Applicability and requirements.

(a) The requirements of 335-14-7-.06 apply to recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, platinum, palladium, iridium, osmium, rhodium, ruthenium, or any combination of these.

(b) Persons who generate, transport or store recyclable materials that are regulated under 335-14-7-.06 are subject to the following requirements:

1. Notification requirements under 335-14-3-.01(8), 335-14-4-.01(2), 335-14-5-.02(2);

2. Rule 335-14-3-.02 (for generators), 335-14-4-.02(1) and (2) (for transporters), and 335-14-6-.05(2) and (3) (for persons who store); and

3. For precious metals exported to or imported from other countries for recovery, 40 CFR part 262, subpart H [incorporated by reference at 335-14-3-.09] and 335-14-6-.02(3).

(c) Persons who store recycled materials that are regulated under 335-14-7-.06 must keep the following records to document that they are not accumulating these materials speculatively (as defined in 335-14-1-.02):

1. Records showing the volume of these materials stored at the beginning of the calendar year;

2. The amount of these materials generated or received during the calendar year; and

3. The amount of materials remaining at the end of the calendar year.

(d) Recyclable materials that are regulated under 335-14-7-.06 that are accumulated speculatively (as defined in 335-14-1-.02) are subject to all applicable provisions of Chapters 335-14-3, 335-14-4, 335-14-5, 335-14-6, and 335-14-8.

Author: Stephen C. Maurer; Amy P. Zachry; Vernon H. Crockett; Jonah L. Harris.
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335-14-7-.07 Spent Lead-Acid Batteries Being Reclaimed.

(1) Applicability and requirements.

(a) Lead acid batteries that are generated, collected, transported, stored, or regenerated for reclamation purposes may be exempt from certain hazardous waste management requirements. The following table may be used to determine which requirements apply. Alternatively, spent lead-acid batteries may be managed in accordance with the "Universal Waste" rule in 335-14-11.

If the batteries *	**And if the batteries**	**Then the batteries**	**And the batteries**
1. will be reclaimed through regeneration (such as by electrolyte replacement).		are exempt from the requirements of 335-14-3 (except for 335-14-3-.01(2)) through 335-14-9	are subject to the requirements of 335-14-2 and 335-14-3-.01(2).
2. will be reclaimed other than through regeneration.	are generated, collected, and/ or transported.	are exempt from the requirements of 335-14-3 (except for 335-14-3-.01(2) through 335-14-8	are subject to the requirements of 335-14-2 and 335-14-3-.01(2), and applicable provisions under 335-14-9.
3. will be reclaimed other than through regeneration.	are stored prior to reclamation by persons other than the person reclaiming the batteries	are exempt from the requirements of 335-14-3 (except for 335-14-3-.01(2) through 335-14-8	are subject to the requirements of 335-14-2 and 335-14-3-.01(2), and applicable provisions under 335-14-9.
4. will be reclaimed other than through regeneration.	are stored prior to reclamation by the person reclaiming the batteries	are subject to the requirements of 335-14-7-.07 (1)(b) and other applicable regulatory provisions described in 335-14-7-.07(1)(b).	are subject to the requirements of 335-14-2 and 335-14-3-.01(2), and applicable provisions under 335-14-9.
5. will be reclaimed other than through regeneration.	are not stored prior to being reclaimed	are exempt from the requirements of 335-14-3 (except for 335-14-3-.01(2) through 335-14-8.	are subject to the requirements of 335-14-2, 335-14-3-.01(2), and applicable provisions under 335-14-9.

If the batteries *	And if the batteries	Then the batteries	And the batteries
6. will be reclaimed through regeneration or any other means.	export these batteries for reclamation in a foreign country.	are exempt from the requirements of 335-14-3 [except for 335-14-3-.01(2) 335-14-3-. 01(8),and 335-14-3-.09] through 335-14-9 and the notificataion requirements at section 3010 of RCRA.	are subject to the requirements of 335-14-2, 335-14-3-.01(2), 335-14-1-.0(8), and 335-14-3-. 09.
7. will be reclaimed through regeneration and any other means.	transport these batteries in the U.S. to export them for reclamation in a foreign country.	are exempt from the requirements of 335-14-4 through 335-14-9 and the notification requirements of section 3010 of RCRA.	must comply with applicable requirements in 335-14-3-.09.
8. will be reclaimed other than through regeneration	Import these batteries from foreign country and store these batteries but you aren't the reclaimer	are exempt from 335-14-3 [except for 335-14-3-.01(2), 335-14-3-.01(8), and 335-14-3-. 09] through 335-14-8 and the notification requirements of section 3010 of RCRA.	are subject to 335-14-2, 335-14-3-.01(2), 335-14-3-.01(8), 335-14-3-.09, and applicable provisions under 335-14-9.
9. will be reclaimed other than through regeneration	Import these batteries from foreign country and store these batteries before you reclaim them	must comply with 335-14-7-.07(1) (b) and as appropriate other regulatory provisions described in 266.80(b).	are subject to 335-14-2, 335-14-3-.01(2), 335-14-3-.01(8), 335-14-3-.09, and applicable provisions under 335-14-9.

If the batteries *	And if the batteries	Then the batteries	And the batteries
10. will be reclaimed other than through regeneration	Import these batteries from foreign country and don't store these batteries before you reclaim them	are exempt from 335-14-3 [except for 335-14-3-.01(2), 335-14-3-.01(8), and 335-14-3-.09] through 335-14-8 and the notification requirements at section 3010 of RCRA.	are subject to 335-14-2, 335-14-3-.01(2), 335-14-3-.01(8), 335-14-3-.09, and applicable provisions under 335-14-9.

(b) The requirements of 335-14-7-.07(1)(b) apply if spent lead-acid batteries are stored prior to reclamation if such reclamation involves any method other than regeneration. The requirements may vary depending upon the RCRA permit status of the person(s) storing and reclaiming the batteries.

1. Interim Status Facilities must comply with:

(i) Notification requirements under 335-14-3-.01(8).

(ii) All applicable provisions in 335-14-6-.01.

(iii) All applicable provisions in 335-14-6-.02 except 335-14-6-.02(4) (waste analysis).

(iv) All applicable provisions in 335-14-6-.03 and 336-14-6-.04.

(v) All applicable provisions in 335-14-6-.05 except 335-14-6-.05(2) and (3) (dealing with the use of the manifest and manifest discrepancies).

(vi) All applicable provisions in 335-14-6-.06 through 335-14-6-.12.

(vii) All applicable provisions in 335-14-8.

2. Permitted Facilities must comply with:

(i) Notification requirements under 335-14-3-.01(8).

(ii) All applicable provisions in 335-14-5-.01.

(iii) All applicable provisions in 335-14-5-.02 except 335-14-5-.02(4) (waste analysis).

(iv) All applicable provisions in 335-14-5-.03 and 336-14-5-.04.

(v) All applicable provisions in 335-14-5-.05 (but not 335-14-5-.05(2) and (3) (dealing with the use of the manifest and manifest discrepancies)).

(vi) All applicable provisions in 335-14-5-.06 through 335-14-5-.12.

(vii) All applicable provisions in 335-14-8.

(2) [Reserved]

(3) Generation.

(a) Facilities which by battery-breaking operations generate separate components of a spent lead-acid battery, which are a solid waste as identified by 335-14-2-.01 and a hazardous waste as identified by 335-14-2-.03 or 335-14-2-.04, must comply with the generator requirements of 335-14-3.

(b) Facilities which generate separate components of a lead-acid battery by battery-breaking operations and offer said components for transportation activities as identified in 335-14-1-.02 must comply with the manifest requirements of 335-14-3-.02 provided the components are a solid waste as identified by 335-14-2-.01 and a hazardous waste as defined by 335-14-2-.03 or 335-14-2-.04.

(c) Facilities which generate components of a spent lead-acid battery, which are a solid waste as identified by 335-14-2-.01 and a hazardous waste as identified by 335-14-2-.03 or 335-14-2-.04, by battery-breaking operations must comply with the storage requirements of 335-14-5-.09(6) and 335-14-5-.10 for each component.

(4) Transportation.

(a) Facilities which engage in transportation activities as identified in 335-14-1-.02 of separate components of a spent lead-acid battery, which are a solid waste as identified by 335-14-2-.01 and a hazardous waste as identified by 335-14-2-.03 or 335-14-2-.04, must comply with the standards applicable to transporters of hazardous waste as outlined in 335-14-4.

(b) Facilities which receive and store separate components of a spent lead-acid battery must comply with the manifest requirements of 335-14-5-.05 provided the components are a solid waste as identified by 335-14-2-.01 and a hazardous waste as identified by 335-14-2-.03 or 335-14-2-.04.

(c) The requirements of 335-14-7-.07 do not apply to the transportation of whole spent lead-acid batteries which have not been subjected to battery-breaking operations.

(5) Storage.

(a) Facilities which receive and store separate components of a spent lead-acid battery which are a solid waste as identified by 335-14-2-.01 and a hazardous waste as identified by 335-14-2-.03 or 335-14-2-.04 must comply with the storage requirements of 335-14-5-.09(6) and 335-14-5-.10 and the permitting requirements of 335-14-8.

(b) Reserved

(6) Treatment and/or disposal.

(a) Facilities which treat or dispose of hazardous waste(s) generated from the reclamation of spent lead-acid batteries are subject to the requirements of 335-14-1 through 335-14-6, 335-14-8, and 335-14-9.

(b) Reserved.

Author: Stephen C. Maurer; Steven O. Jenkins; Michael Champion; Robert W. Barr; C. Edwin Johnston; Bradley N. Curvin; Heather M. Jones; Vernon H. Crockett; Jonah L. Harris
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335-14-7-.08 Subpart H - Hazardous Waste Burned In Boilers And Industrial Furnaces.

The Environmental Protection Agency Regulations 40 CFR Part 266, Subpart H (as published by EPA on January 4, 1985 and February 21, 1991, and as amended on July 17, 1991; August 27, 1991; August 25, 1992; September 30, 1992; November 9, 1993; July 20, 1993; June 29, 1995; June 13, 1997; September 30, 1999; June 14; 2005; April 4, 2006; July 14, 2006; March 18, 2010; March 20, 2023; and August 9, 2023) except §266.108, designated in Rules 335-14-7-.08(1) through 335-14-7-.08(8) and Rules 335-14-7-.08(10) through 335-14-7-.08(13), are incorporated herein by reference as set forth in 40 CFR, Part 266.

In the event that any Code of Federal Regulations Rule(s) incorporated herein by reference refers to or cites another Code of Federal Regulations Rule(s), other than 40 CFR Part 264, Subpart BB, such reference to the other Code of Federal Regulations Rule(s) is not incorporated herein and the ADEM Administration Code rule specifically addressing said issue or circumstance shall take precedence, be applicable and govern.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.

(1) §266.100 Applicability (as published by EPA on February 21, 1991 and amended August 9, 2023).

(2) §266.101 Management prior to burning (as published by EPA on February 21, 1991 and amended on August 25, 1992; September 30; 1999; and March 18, 2010).

(3) §266.102 Permit standards for burners (as published by EPA on February 21, 1991 and amended on July 17, 1991; August 27, 1991; June 14, 2005; April 4, 2006; and July 14; 2006).

(4) §266.103 Interim status standards for burners (as published by EPA on February 21, 1991 and amended on July 17, 1991; August 27, 1991; August 25, 1992; September 30, 1992; June 29, 1995; April 4, 2006; and July 14, 2006).

(5) §266.104 Standards to control organic emissions (as published by EPA on February 21, 1991 and as amended on July 17, 1991; August 25, 1992; July 20, 1993; June 29, 1995; June 13, 1997; and March 20, 2023).

(6) §266.105 Standards to control particulate matter (as published by EPA on February 21, 1991 and amended on September 30, 1999).

(7) §266.106 Standards to control metals emissions (as published by EPA on February 21, 1991 and amended on July 17, 1991; August 25, 1992; July 20, 1993; June 13, 1997; June 14, 2005; and July 14, 2006).

(8) §266.107 Standards to control hydrogen chloride (HCl) and chlorine gas (Cl2) emissions (as published by EPA on February 21, 1991 and amended on July 17, 1991; August 25, 1992; and June 13, 1997).

(9) Small Quantity on-site burner exemption.

(a) Exempt quantities. Owners and operators of facilities that burn hazardous waste generated on-site in an on-site boiler or industrial furnace are exempt from the requirements of 335-14-7-.08 provided that:

1. The quantity of hazardous waste burned in a device for a calendar month does not exceed the limits provided in the following table based on the terrain adjusted effective stack height as defined in §266.106(b)(3) of 40 CFR:

EXEMPT QUANTITIES FOR SMALL QUANTITY BURNER EXEMPTION

Terrain-adjusted effective stack height of device (meters)	Allowable hazardous waste burning rate (gallons/Month)	Terrain-Adjusted effective stack height of device (meters)	Allowable hazardous waste burning rate (gallons/Month)
0 to 3.9	0	40.0 to 44.9	210
4.0 to 5.9	13	45.0 to 49.9	260
6.0 to 7.9	18	50.0 to 54.9	330
8.0 to 9.9	27	55.0 to 59.9	400
10.0 to 11.9	40	60.0 to 64.9	490
12.0 to 13.9	48	65.0 to 69.9	610
14.0 to 15.9	59	70.0 to 74.9	680
16.0 to 17.9	69	75.0 to 79.9	760
18.0 to 19.9	76	80.0 to 84.9	850
20.0 to 21.9	84	85.0 to 89.9	960
22.0 to 23.9	93	90.0 to 94.9	1,100
24.0 to 25.9	100	95.0 to 99.9	1,200
26.0 to 27.9	110	100.0 to 104.9	1,300
28.0 to 29.9	130	105.0 to 109.9	1,500
30.0 to 34.9	140	110.0 to 114.9	1,700
35.0 to 39.9	170	115.0 or greater	1,900

2. The maximum hazardous waste firing rate does not exceed at any time one percent of the total fuel requirements for the device (hazardous waste plus other fuel) on a total heat input, or mass input basis, whichever results in the lower mass feed rate of hazardous waste.

3. The hazardous waste has a minimum heating value of 5,000 Btu/lb, as generated; and

4. The hazardous waste fuel does not contain (and is not derived from) EPA Hazardous Waste Nos. F020, F021, F022, F023, F026, or F027.

(b) Mixing with nonhazardous fuels. If hazardous waste fuel is mixed with a nonhazardous fuel, the quantity of hazardous waste before such mixing is used to comply with 335-14-7-.08(9)(a)

(c) Multiple stacks. If an owner or operator burns hazardous waste in more than one on-site boiler or industrial furnace exempt under 335-14-7-.08(9), the quantity limits provided by 335-14-7-.08(9)(a)1. are implemented according to the following equation:

where:

n means the number of stacks;

Actual Quantity Burned means the waste quantity burned per month in device "i";

Allowable Quantity Burned means the maximum allowable exempt quantity for stack "i" from the table in 335-14-7-.08(9)(a)1.

Note 1: This exemption does not relieve the facility from the necessity of obtaining appropriate Air Permits from the Department which would authorize the use of alternate feed streams.

Note 2: Hazardous wastes that are subject to the conditions for exemption for very small quantity generators under 335-14-3-.01(4) may be burned in an off-site device under the exemption provided by 335-14-7-.08(9) but must be included in the quantity determination for the exemption.

(d) Notification requirements. The owner or operator of facilities qualifying for the small quantity burner exemption under 335-14-7-.08(9) must provide a one-time signed, written notice to EPA and ADEM indicating the following:

1. The combustion unit is operating as a small quantity burner of hazardous waste;

2. The owner and operator are in compliance with the requirements of 335-14-7-.08(9); and

3. The maximum quantity of hazardous waste that the facility may burn per month as provided by 335-14-7-.08(9)(a)1.

(e) Recordkeeping requirements. The owner or operator must maintain at the facility for at least three years sufficient records documenting compliance with the hazardous waste quantity, firing rate, and heating value limits of 335-14-7-.08(9) and any other parameters deemed necessary by the Department. At a minimum, these records must indicate the quantity of hazardous waste and other fuel burned in each unit per calendar month, and the heating value of the hazardous waste.

(f) Monitoring requirements.

1. The combustion device shall be operated in conformance with the carbon monoxide controls

provided by §266.104(b)(1) and (b)(2). Devices subject to the exemption provided by 335-14-7-.08(9) are not eligible for the alternative carbon monoxide controls provided by §266.104(c).

2. Additional or alternative monitoring techniques may be required on a case-by-case basis by the Director.

(g) Automatic waste feed cutoff. A boiler or industrial furnace must be operated with a functioning system that automatically cuts off the hazardous waste feed when operating conditions specified in 335-14-7-.08(9)(f) are exceeded.

(h) Start-up and shut-down. Hazardous waste must not be fed into the device during start-up and shut-down of the boiler or industrial furnace unless the device is operating within the conditions of operation specified in the Air Permit.

(10) §266.109 Low risk waste exemption (as published by EPA on February 21, 1991 and amended on July 17, 1991; August 27, 1991; and July 14, 2006).

(11) §266.110 Waiver of DRE trial burn for boilers (as published by EPA on February 21, 1991 and amended on July 17 1991; and August 27, 1991).

(12) §266.111 Standards for direct transfer (as published by EPA on January 4, 1985 and amended on August 27, 1991).

(13) §266.112 Regulation of residues (as published by EPA on January 4, 1985 and amended on August 27, 1991; August 25, 1992; November 9, 1993; September 30, 1999; and June 14, 2005).

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335-14-7-.09 Reserved.
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335-14-7-.10 Reserved.
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335-14-7-.11 Reserved.
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335-14-7-.12 Reserved.
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History:

335-14-7-.13 Military Munitions.

(1) Applicability.

(a) The regulations in 335-14-7-.13 identify when military munitions become a solid waste, and, if these wastes are also hazardous under 335-14-7-.13 or 335-14-2, the management standards that apply to these wastes.

(b) Unless otherwise specified in 335-14-7-.13, all applicable requirements in 335-14-1 through 335-14-9 apply to waste military munitions.

(2) [Reserved]

(3) Definition of solid waste.

(a) A military munition is not a solid waste when:

1. Used for its intended purpose, including:

(i) Use in training military personnel or explosives and munitions emergency response specialists (including training in proper destruction of unused propellant or other munitions); or

(ii) Use in research, development, testing, and evaluation of military munitions, weapons, or weapon systems; or

(iii) Recovery, collection, and on-range destruction of unexploded ordnance and munitions fragments during range clearance activities at active or inactive ranges. However, ''use for intended purpose'' does not include the on-range disposal or burial of unexploded ordnance and contaminants when the burial is not a result of product use.

2. An unused munition, or component thereof, is being repaired, reused, recycled, reclaimed, disassembled, reconfigured, or otherwise subjected to materials recovery activities, unless such activities involve use constituting disposal as defined in 335-14-2-.01(2)(c)1., or burning for energy recovery as defined in 335-14-2-.01(2)(c)2.

(b) An unused military munition is a solid waste when any of the following occurs:

1. The munition is abandoned by being disposed of, burned, detonated (except during intended use as specified in 335-14-7-.13(3)(a)), incinerated, or treated prior to disposal; or

2. The munition is removed from storage in a military magazine or other storage area for the purpose of being disposed of, burned, or incinerated, or treated prior to disposal, or

3. The munition is deteriorated or damaged (e.g., the integrity of the munition is compromised by cracks, leaks, or other damage) to the point that it cannot be put into serviceable condition, and cannot reasonably be recycled or used for other purposes; or

4. The munition has been declared a solid waste by an authorized military official.

(c) A used or fired military munition is a solid waste:

1. When transported off range or from the site of use, where the site of use is not a range, for the purposes of storage, reclamation, treatment, disposal, or treatment prior to disposal; or

2. If recovered, collected, and then disposed of by burial, or landfilling either on or off a range.

(d) For purposes of RCRA section 1004(27), a used or fired military munition is a solid waste, and, therefore, is potentially subject to RCRA corrective action authorities under sections 3004(u) and (v), and 3008(h), or imminent and substantial endangerment authorities under section 7003, if the munition lands off-range and is not promptly rendered safe and/or retrieved. Any imminent and substantial threats associated with any remaining material must be addressed. If remedial action is infeasible, the operator of the range must maintain a record of the event for as long as any threat remains. The record must include the type of munition and its location (to the extent the location is known).

(4) Standards applicable to the transportation of solid waste military munitions.

(a) Criteria for hazardous waste regulation of waste non-chemical military munitions in transportation.

1. Waste military munitions that are being transported and that exhibit a hazardous waste characteristic or are listed as hazardous waste under 335-14-2, are listed or identified as a hazardous waste (and thus are subject to regulation under 335-14-1 through 335-14-9), unless all the following conditions are met:

(i) The waste military munitions are not chemical agents or chemical munitions;

(ii) The waste military munitions must be transported in accordance with the Department of Defense shipping controls applicable to the transport of military munitions;

(iii) The waste military munitions must be transported from a military owned or operated installation to a military owned or operated treatment, storage, or disposal facility; and

(iv) The transporter of the waste must provide oral notice to the Department within 24 hours from the time the transporter becomes aware of any loss or theft of the waste military munitions, or any failure to meet a condition of 335-14-7-.13(4)(a)1. that may endanger health or the environment. In addition, a written submission describing the circumstances shall be provided within 5 days from the time the transporter becomes aware of any loss or theft of the waste military munitions or any failure to meet a condition of 335-14-7-.13(4)(a)1.

2. If any waste military munitions shipped under 335-14-7-.13(4)(a)1. are not received by the receiving facility within 45 days of the day the waste was shipped, the owner or operator of the receiving facility must report this non-receipt to the Department within 5 days.

3. The exemption in 335-14-7-.13(4)(a)1. from regulation as hazardous waste shall apply only to the transportation of non-chemical waste military munitions. It does not affect the regulatory status of waste military munitions as hazardous wastes with regard to storage, treatment, or disposal.

4. The conditional exemption in 335-14-7-.13(4)(a)1. applies only so long as all of the conditions in 335-14-7-.13(4)(a)1. are met.

(b) Reinstatement of exemption. If any waste military munition loses its exemption under 335-14-7-.13(4)(a)1., an application may be filed with the Department for reinstatement of the exemption from hazardous waste transportation regulation with respect to such munition as soon as the munition is returned to compliance with the conditions of 335-14-7-.13(4)(a)1. If the Department finds that reinstatement of the exemption is appropriate based on factors such as the transporter's provision of a satisfactory explanation of the circumstances of the violation, or a demonstration that the violations are not likely to recur, the Department may reinstate the exemption under 335-14-7-.13(4)(a)1. If the Department does not take action on the reinstatement application within 60 days after receipt of the application, then reinstatement shall be deemed granted, retroactive to the date of the application. However, the Department may terminate a conditional exemption reinstated by default in the preceding sentence if the Department finds that reinstatement is inappropriate based on factors such as the transporter's failure to provide a satisfactory explanation of the circumstances of the violation, or failure to demonstrate that the violations are not likely to recur. In reinstating the exemption under 335-14-7-.13(4)(a)1., the Department may specify additional conditions as are necessary to ensure and document proper transportation to protect human health and the environment.

(c) Amendments to DOD shipping controls. The Department of Defense shipping controls applicable to the transport of military munitions referenced in 335-14-7-.13(4)(a)1.(ii) are Government Bill of Lading (GBL) (GSA Standard Form 1109), requisition tracking form DD Form 1348, the Signature and Talley Record (DD Form 1907), Special Instructions for Motor Vehicle Drivers (DD Form 836), and the Motor Vehicle Inspection Report (DD Form 626) in effect on November 8, 1995, except as provided in the following sentence. Any amendments

to the Department of Defense shipping controls shall become effective for purposes of 335-14-7-.13(4)(a)1. on the date the Department of Defense publishes notice in the Federal Register that the shipping controls referenced in 335-14-7-.13(4)(a)1. (ii) have been amended.

(5) Standards applicable to emergency responses.

(a) Explosives and munitions emergencies involving military munitions or explosives are subject to 335-14-3-.01(i), 335-14-4-.01(1)(e), 335-14-5-.01(1)(g)8., 335-14-6-.01(1)(c)11., and 335-14-8-.01(1)(c)3., or alternatively to 335-14-8-.06(1).

(6) Standards applicable to the storage of solid waste military munitions.

(a) Criteria for hazardous waste regulation of waste non-chemical military munitions in storage.

1. Waste military munitions in storage that exhibit a hazardous waste characteristic or are listed as hazardous waste under 335-14-2, are listed or identified as a hazardous waste (and thus are subject to regulation under 335-14-1 through 335-14-17), unless all the following conditions are met:

(i) The waste military munitions are not chemical agents or chemical munitions.

(ii) The waste military munitions must be subject to the jurisdiction of the Department of Defense Explosives Safety Board (DDESB).

(iii) The waste military munitions must be stored in accordance with the DDESB storage standards applicable to waste military munitions.

(iv) Within 90 days of March 27, 1998 or within 90 days of when a storage unit is first used to store waste military munitions, whichever is later, the owner or operator must notify the Department of the location of any waste storage unit used to store waste military munitions for which the conditional exemption in 335-14-7-.13(6)(a)1. is claimed.

(v) The owner or operator must provide oral notice to the Department within 24 hours from the time the owner or operator becomes aware of any loss or theft of the waste military munitions, or any failure to meet a condition of 335-14-7-.13(6)(a)1. that may endanger health or the environment. In addition, a written submission describing the circumstances shall

be provided within 5 days from the time the owner or operator becomes aware of any loss or theft of the waste military munitions or any failure to meet a condition of 335-14-7-.13(6)(a)1.

(vi) The owner or operator must inventory the waste military munitions at least annually, must inspect the waste military munitions at least quarterly for compliance with the conditions of 335-14-7-.13(6)(a)1., and must maintain records of the findings of these inventories and inspections for at least three years.

(vii) Access to the stored waste military munitions must be limited to appropriately trained and authorized personnel.

2. The conditional exemption in 335-14-7-.13(6)(a)1. from regulation as hazardous waste shall apply only to the storage of non-chemical waste military munitions. It does not affect the regulatory status of waste military munitions as hazardous wastes with regard to transportation, treatment, or disposal.

3. The conditional exemption in 335-14-7-.13(6)(a)1. applies only so long as all of the conditions in 335-14-7-.13(6)(a)1. are met.

(b) Notice of termination of waste storage. The owner or operator must notify the Department when a storage unit identified in 335-14-7-.13(6)(a)1.(iv) will no longer be used to store waste military munitions.

(c) Reinstatement of conditional exemption. If any waste military munition loses its conditional exemption under 335-14-7-.13(6)(a)1., an application may be filed with the Department for reinstatement of the conditional exemption from hazardous waste storage regulation with respect to such munition as soon as the munition is returned to compliance with the conditions of 335-14-7-.13(6)(a)1. If the Department finds that reinstatement of the conditional exemption is appropriate based on factors such as the owner’s or operator’s provision of a satisfactory explanation of the circumstances of the violation, or a demonstration that the violations are not likely to recur, the Department may reinstate the conditional exemption under 335-14-7-.13(6)(a)1. If the Department does not take action on the reinstatement application within 60 days after receipt of the application, then reinstatement shall be deemed granted, retroactive to the date of the application. However, the Department may terminate a conditional exemption reinstated by default in the preceding sentence if he/she finds that reinstatement is inappropriate based on factors such as the owner’s or operator’s failure to

provide a satisfactory explanation of the circumstances of the violation, or failure to demonstrate that the violations are not likely to recur. In reinstating the conditional exemption under 335-14-7-.13(6)(a)1., the Department may specify additional conditions as are necessary to ensure and document proper storage to protect human health and the environment.

(d) Waste chemical munitions.

1. Waste military munitions that are chemical agents or chemical munitions and that exhibit a hazardous waste characteristic or are listed as hazardous waste under 335-14-2, are listed or identified as a hazardous waste and shall be subject to the applicable regulatory requirements of RCRA subtitle C.

2. Waste military munitions that are chemical agents or chemical munitions and that exhibit a hazardous waste characteristic or are listed as hazardous waste under 335-14-2, are not subject to the storage prohibition in RCRA section 3004(j), codified at 335-14-9-.05(1).

(e) Amendments to DDESB storage standards. The DDESB storage standards applicable to waste military munitions, referenced in 335-14-7-.13(6)(a)1.(iii), are DOD 6055.9-STD ("DOD Ammunition and Explosive Safety Standards"), in effect on November 8, 1995, except as provided in the following sentence. Any amendments to the DDESB storage standards shall become effective for purposes of 335-14-7-.13(6)(a)1. on the date the Department of Defense publishes notice in the Federal Register that the DDESB standards referenced in 335-14-7-.13(6)(a)1. have been amended.

(7) Standards applicable to the treatment and disposal of waste military munitions. The treatment and disposal of hazardous waste military munitions are subject to the applicable permitting, procedural, and technical standards in 335-14-1 through 335-14-9.
Author: C. Edwin Johnston, Bradley N. Curvin; Jonah L. Harris
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 24, 2009; effective March 31, 2009. **Amended:** Published November 20, 2022; effective June 12, 2023.

335-14-7-.14 Conditional Exemption For Low-Level Mixed Waste Storage, Treatment, Transportation, And Disposal.

(1) [Reserved].

(2) Storage and treatment conditional exemption applicability. The storage and treatment conditional exemption exempts LLMW from the regulatory definition of hazardous waste in 335-14-2-.01(3) if the waste meets the eligibility criteria in 335-14-7-.14(3) and the generator meets the conditions in 335-14-7-.14(4).

(3) Storage and treatment conditional exemption eligibility. LLMW is eligible for this conditional exemption if it is generated and managed under a single NRC or NRC Agreement State license. (Mixed waste generated at a facility with a different license number and shipped to another facility for storage or treatment requires a permit and is ineligible for this exemption. In addition, NARM waste is ineligible for this exemption.)

(4) Storage and treatment conditional exemption generator conditions.

(a) In order for LLMW to qualify for this exemption, the generator must notify the Department in writing by certified delivery that a conditional exemption for the stored LLMW is being claimed. The dated notification must include the generator's name, location address, EPA identification number, NRC or NRC Agreement State license number, the waste code(s) and storage unit(s) for which the exemption is sought, and a statement that the conditions of 335-14-7-.14(4) have been met. The notification must be signed by an authorized representative who certifies that the information in the notification is true, accurate, and complete. The Department must receive the notification either within 90 days after the effective date of this rule or within 90 days after a storage unit is first used to store conditionally exempt LLMW.

(b) To qualify for and maintain an exemption for LLMW, the generator must:

1. Store the waste in tanks or containers in compliance with the requirements of the NRC or NRC Agreement State license that apply to the proper storage of LLW (not including those license requirements that relate solely to recordkeeping);

2. Store the waste in tanks or containers in compliance with chemical compatibility requirements of a tank or container in 335-14-5-.09(8), 335-14-5-.10(10), 335-14-6-.09(8), or 335-14-6-.10(10);

3. Certify that facility personnel who manage stored conditionally exempt LLMW are trained in a manner that ensures that the conditionally exempt waste is safely managed and includes training in chemical waste management and hazardous materials incidents response that meets the personnel training standards found in 335-14-6-.02(7)(a)3.;

4. Conduct an inventory of stored conditionally exempt LLMW at least annually (no more than 365 days from the date of the previous annual inventory) and inspect it at least quarterly (no more than 90 days from the date of the previous quarterly inspection) for compliance with 335-14-7-.14; and

5. Maintain an accurate emergency plan and provide it to all local authorities who may have to respond to a fire, explosion, or release of hazardous waste or hazardous constituents. The plan must describe emergency response arrangements with local authorities; describe evacuation plans; list the names, addresses, and telephone numbers of all facility personnel qualified to work with local authorities as emergency coordinators; and list emergency equipment.

(5) Storage and treatment conditional exemption waste treatment. The generator may treat LLMW within a tank or container in accordance with the terms of the generator's NRC or NRC Agreement State license and the Alabama Hazardous Waste Management and Minimization Act. Treatment that cannot be done in a tank or container without a RCRA permit (such as incineration) is not allowed under this exemption.

(6) Loss of storage and treatment conditional exemption.

(a) LLMW will automatically lose the storage and treatment conditional exemption if the generator fails to meet any of the conditions specified in 335-14-7-.14(4). LLMW that has lost the exemption must immediately be managed as RCRA hazardous waste and the storage unit storing the LLMW immediately becomes subject to RCRA hazardous waste container and/or tank storage requirements.

1. A generator who fails to meet any of the conditions specified in 335-14-7-.14(4) must report to ADEM and the NRC, or the oversight agency in the NRC Agreement State, in writing by certified delivery within 30 days after learning of the failure. The report must be signed by an authorized representative certifying that the information provided is true, accurate, and complete. This report must include:

(i) The specific condition(s) which the generator failed to meet;

(ii) A description of the LLMW (including the waste name, hazardous waste codes and quantity) and storage location at the facility; and

(iii) The date(s) on which the failure(s) occurred.

2. If the failure to meet any of the conditions may endanger human health or the environment, the generator must also immediately notify ADEM orally within 24 hours and follow up with a written notification within five days after the failure. Failures that may endanger human health or the environment include, but are not limited to, discharge of a CERCLA reportable quantity or other leaking or exploding tanks or containers, or detection of radionuclides above background or hazardous constituents in the leachate collection system of a storage area. If the failure may endanger human health or the environment, the provisions of the emergency plan must be implemented.

(b) The Department may terminate the conditional exemption for LLMW, or require additional conditions to claim a conditional exemption, for serious or repeated noncompliance with any requirement(s) of 335-14-7-.14.

(7) Reclaiming a lost storage and treatment conditional exemption.

(a) A generator may reclaim a lost storage and treatment exemption for LLMW if:

1. The conditions specified in 335-14-7-.14(4) are met; and

2. The generator notifies ADEM by certified delivery that a lost exemption for LLMW is being reclaimed. The notice must be signed by an authorized representative certifying that the information contained in the notice is true, complete, and accurate. The notice must:

(i) Explain the circumstances of each failure.

(ii) Certify that the generator has corrected each failure that caused the exemption for LLMW to be lost and that the generator again meets all the conditions as of the date of the notice.

(iii) Describe plans that have been implemented, listing specific steps taken, to ensure the conditions will be met in the future.

(iv) Include any other information ADEM should consider when reviewing the notice reclaiming the exemption.

(b) The Department may terminate a reclaimed conditional exemption if the generator's claim is found to be inappropriate based on factors including, but not limited to, the following: failure to correct the problem; unsatisfactory explanation of the circumstances of the failure; or failure to implement a plan with steps to prevent another failure to meet

the conditions of 335-14-7-.14(4). In reviewing a reclaimed conditional exemption under this section, the Department may add conditions to the exemption to ensure that waste management during storage and treatment of the LLMW will protect human health and the environment.

(8) Storage and treatment conditional exemption recordkeeping.

(a) In addition to those records required by the NRC or NRC Agreement State license, the following records must be maintained:

1. Initial notification records, return receipts, reports of failure(s) to meet the exemption conditions, and all records supporting any reclaim of an exemption;

2. Records of LLMW annual inventories and quarterly inspections;

3. Certification that facility personnel who manage stored mixed waste are trained in safe management of LLMW including training in chemical waste management and hazardous materials incidents response; and

4. Emergency plan as specified in 335-14-7-.14(4)(b).

(b) Records concerning notification, personnel trained, and the emergency plan must be maintained for as long as this exemption is claimed and for three years thereafter, or in accordance with NRC regulations under 10 CFR part 20 (or equivalent NRC Agreement State regulations), whichever is longer. Records concerning annual inventories and quarterly inspections must be maintained for three years after the waste is sent for disposal, or in accordance with NRC regulations under 10 CFR part 20 (or equivalent NRC Agreement State regulations), whichever is longer.

(9) Storage and treatment conditional exemption ineligibility.

(a) When LLMW has met the requirements of the generator's NRC or NRC Agreement State license for decay-in-storage and can be disposed of as non-radioactive waste, then the conditional exemption for storage no longer applies. On that date, the waste is subject to hazardous waste regulation under the relevant sections of 335-14-1 through 335-14-9, and the time period for accumulation of a hazardous waste as specified in 335-14-3-.01(6) or (7) begins.

(b) When conditionally exempt LLMW which has been generated and stored under a single NRC or NRC Agreement State license number is removed from storage, it is no longer eligible for the storage and treatment exemption. However, the waste may be

eligible for the transportation and disposal conditional exemption at 335-14-7-.14(11).

(10) Storage unit closure. Interim status and permitted storage units that have been used to store only LLMW prior to the effective date of 335-14-7-.14 and, after that date, store only LLMW which becomes exempt under 335-14-7-.14, are not subject to the closure requirements of 335-14-5 and 335-14-6. Storage units (or portions of units) that have been used to store both LLMW and non-mixed hazardous waste prior to the effective date of 335-14-7-.14 or are used to store both after that date remain subject to closure requirements with respect to the non-mixed hazardous waste.

(11) Transportation and disposal conditional exemption applicability. The transportation and disposal conditional exemption exempts waste from the regulatory definition of hazardous waste in 335-14-2-.01(3) if the waste meets the eligibility criteria of 335-14-7-.14(12) and the generator meets the conditions in 335-14-7-.14(13).

(12) Transportation and disposal conditional exemption eligibility.

(a) Eligible waste must be:

1. A LLMW, as defined in 335-14-1.02, that meets the waste acceptance criteria of a LLRWDF; and/or

2. An eligible NARM waste, defined in 335-14-1-.02.

(b) Reserved.

(13) Transportation and disposal conditional exemption conditions.

(a) To qualify for and maintain the transportation and disposal conditional exemption, the following conditions must be met:

1. The eligible waste must meet or be treated to meet LDR treatment standards, as described in 335-14-7-.14(14).

2. The generator must manifest and transport the exempted waste according to NRC regulations, as described in 335-14-7-.14(15).

3. The exempted waste must be in containers when it is disposed of in the LLRWDF, as described in 335-14-7-.14(18).

4. The exempted waste must be disposed of at a designated LLRWDF, as described in 335-14-7-.14(17).

(b) Reserved.

(14) Transportation and disposal conditional exemption treatment standards. LLMW or eligible NARM waste must meet LDR treatment standards specified in 335-14-9-.04.

(15) Transportation and disposal conditional exemption manifest and transportation condition. If the generator is not already subject to NRC or NRC Agreement State equivalent manifest and transportation regulations for the shipment of waste, the generator must meet the manifest requirements under 10 CFR 20.2006 (or NRC Agreement State equivalent regulations) and the transportation requirements under 10 CFR 1.5 (or NRC Agreement State equivalent regulations) to ship the exempted waste.

(16) Transportation and disposal conditional exemption effective date.

(a) The exemption becomes effective once all the following have occurred:

1. The eligible waste meets the applicable LDR treatment standards;

2. The generator has received return receipts confirming notification of ADEM and the LLRWDF, as described in 335-14-7-.14(19);

3. The waste has been packaged and prepared for shipment according to NRC Packaging and Transportation regulations found under 10 CFR 71 (or NRC Agreement State equivalent regulations) and a manifest has been prepared according to NRC manifest regulations found under 10 CFR 20 (or NRC Agreement State equivalent regulations); and

4. The waste has been placed on a transportation vehicle destined for a LLRWDF licensed by NRC or an NRC Agreement State.

(b) Reserved.

(17) Transportation and disposal conditional exemption acceptable disposal facilities. Exempted waste must be disposed of in a LLRWDF that is regulated and licensed by NRC under 10 CFR 61 or by an NRC Agreement State under equivalent State regulations, including State of Alabama NARM licensing regulations for eligible NARM.

(18) Transportation and disposal conditional exemption container requirements.

(a) Exempted waste must be placed in containers before it is disposed.

(b) The container must be:

1. A carbon steel drum; or

2. An alternative container with equivalent containment performance in the disposal environment as a carbon steel drum; or

3. A high integrity container as defined by NRC.

(19) Transportation and disposal conditional exemption notification requirements.

(a) A one-time notice must be provided to ADEM stating that the transportation and disposal conditional exemption is being claimed prior to the initial shipment of an exempted waste to a LLRWDF. The dated written notice, sent by certified delivery, must include facility name, address, phone number, and EPA identification number.

(b) The LLRWDF receiving the exempted waste must be notified by certified delivery before each shipment of exempted waste. The waste must not be shipped until after the generator has received the return receipt of the notice to the LLRWDF. This notification must include the following:

1. A statement by the generator claiming the exemption for the waste;

2. A statement that the eligible waste meets applicable LDR treatment standards;

3. The facility's name, address, and EPA identification number;

4. The applicable hazardous waste codes prior to the exemption of the waste streams;

5. A statement that the exempted waste must be placed in a container according to 335-14-7-.14(18) prior to disposal in order for the waste to remain exempt under the transportation and disposal conditional exemption of 335-14-7-.14;

6. The manifest number of the shipment that will contain the exempted waste; and

7. A certification that all the information provided is true, complete, and accurate. An authorized representative of the generator must sign the statement.

(20) Transportation and disposal conditional exemption recordkeeping.

(a) In addition to those records required by an NRC or NRC Agreement State license, the generator must maintain the following records:

1. Documents required by the applicable recordkeeping requirements of 335-14-5-.05(4), 335-14-6-.05(4), and 335-14-9-.07(7) to demonstrate that the waste has met LDR treatment standards prior to claiming the exemption;

2. Copies of all notifications and return receipts required by 335-14-7-.14(21) and 335-14-7-.14(22) for three years after the exempted waste is sent for disposal;

3. Copies of all notifications and return receipts required by 335-14-7-.14(19)(a) for three years after the last exempted waste is sent for disposal;

4. Copies of the notification and return receipts required by 335-14-7-.14(19)(b) for three years after the exempted waste is sent for disposal; and

(b) If not already required by the NRC or NRC Agreement State equivalent manifest and transportation regulations, all other documents related to tracking the exempted waste as required under 10 CFR 20.2006 or NRC Agreement State equivalent regulations, including applicable NARM requirements, in addition to the records specified in 335-14-7-.14(20)(a)1. through 4.

(21) Loss of transportation and disposal conditional exemption.

(a) Any waste will automatically lose the transportation and disposal exemption if the generator fails to manage it in accordance with all of the conditions specified in 335-14-7-.14(13).

1. When failing to meet any of the conditions specified in 335-14-7-.14(13) for any wastes, the generator must report to ADEM, in writing by certified delivery, within 30 days after learning of the failure. The report must be signed by an authorized representative certifying that the information provided is true, accurate, and complete. This report must include:

(i) The specific condition(s) that the generator failed to meet for the waste;

(ii) A description of the waste (including the waste name, hazardous waste codes and quantity) that lost the exemption; and

(iii) The date(s) on which the failure(s) occurred.

2. If the failure to meet any of the conditions may endanger human health or the environment, the generator must also immediately notify ADEM orally within 24 hours and follow up with a written notification within 5 days after learning of the failure.

(b) The Department may terminate a generator's ability to claim a conditional exemption, or require additional conditions to claim a conditional exemption, for serious or repeated noncompliance with any requirement(s) of 335-14-7-.14.

(22) Reclaiming a lost transportation and disposal conditional exemption.

(a) A generator may reclaim the transportation and disposal exemption for a waste after receiving a return receipt confirming that ADEM received a notification of the loss of the exemption specified in 335-14-7-.14(21)(a) and if:

1. The generator again meets the conditions specified in 335-14-7-.14(13) for the waste; and

2. The generator notifies ADEM, by certified delivery, that the exemption for the waste is being reclaimed. The notice must be signed by an authorized representative certifying that the information provided is true, accurate, and complete and must:

(i) Explain the circumstances of each failure;

(ii) Certify that each failure that caused the loss of the exemption for the waste has been corrected and that the generator again meets all conditions for the waste as of the date of the notice;

(iii) Describe plans that have been implemented, listing the specific steps taken, to ensure that conditions will be met in the future; and

(iv) Include any other information ADEM should consider when reviewing the notice reclaiming the exemption.

(b) The Department may terminate a reclaimed conditional exemption if the generator's claim is found to be inappropriate based on factors including, but not limited to: failure to correct the problem; unsatisfactory explanation of the circumstances of the failure; or failure to implement a plan with steps to prevent another failure to meet the conditions of 335-14-7-.14(13). In reviewing a reclaimed conditional exemption under 335-14-7-.14, the Department may add conditions to the exemption to ensure that transportation

and disposal activities will protect human health and the environment.
Author: Michael B. Champion; Vernon H. Crockett; Bradley N. Curvin; Jonah L. Harris
Statutory Authority: Code of Ala. 1975, §§22-30-20, 22-30-19, 22-30-16, 22-30-15, 22-30-14, 22-30-12, 22-30-11, 22-30-10.
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335-14-7-.15 Reserved.
Author:
Statutory Authority:
History:

335-14-7-.16 Hazardous Waste Pharmaceuticals.

(1) Applicability

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to 335-14-3-.01(4) and is not subject to 335-14-7-.16, except for 335-14-7-.16(5) and 335-14-7-.16(7) and the optional provisions of 335-14-7-.16(4).

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with 335-14-7-.16(1)(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with 335-14-3-.01(4) and the optional provisions of 335-14-7-.16(4).

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in 335-14-7-.16(1)(a), a healthcare facility is subject to the following in lieu of 335-14-3 through 335-14-6:

1. Sections 335-14-7-.16(2) and 335-14-7-.16(5) through 335-14-7-.16(8) with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

2. 335-14-7-.16(2)(a), 335-14-7-.16(3), 335-14-7-.16(5) through 335-14-7-.16(7) and 335-14-7-.16(9) with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to 335-14-7-.16(5) through 335-14-7-.16(10) in lieu of 335-14-3 through 335-14-6 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to 335-14-7-.16. Other generators are subject to 335-14-3 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to 335-14-1 through 335-14-11, except as specified:

1. Pharmaceuticals that are not solid waste, as defined by 335-14-2-.01(2) because they are legitimately used/ reused (e.g., lawfully donated for their intended purpose) or reclaimed.

2. Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by 335-14-2-.01(2), because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

3. Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. 335-14-7-.16 does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

4. Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. 335-14-7-.16 does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

5. Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

6. Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. 335-14-7-.16 does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

7. Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in 335-14-7-.16(6)(a)2. and 335-14-7-.16(6)(b).

(2) Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

(a) Notification and withdrawal for healthcare facilities managing hazardous waste pharmaceuticals

1. Notification. A healthcare facility must notify the Department, using ADEM Form 8700-12 (Notification of Regulated Waste Activity) or an electronic method used by the Department, that it is a healthcare facility operating under 335-14-7-.16. A healthcare facility is not required to fill out Schedule A part II.B (Characteristics of Nonlisted Hazardous Waste) and II.C (Listed Hazardous Wastes) of the Notification of Regulated Waste Activity with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Notification of Regulated Waste Activity) for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number must notify the Department that it is a healthcare facility as part of its next

Notification of Regulated Waste Activity, if it is required to submit one; or if not required to submit a Notification of Regulated Waste Activity, within 60 days of the effective date of 335-14-7-.16, or within 60 days of becoming subject to 335-14-7-.16.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the Department that it is a healthcare facility as part of its next Notification of Regulated Waste Activity, if it is required to submit one; or if not required to submit a Notification of Regulated Waste Activity, within 60 days of the effective date of 335-14-7-.16, or within 60 days of becoming subject to 335-14-7-.16.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to 335-14-7-.16.

2. Withdrawal. A healthcare facility that operated under 335-14-7-.16 but is no longer subject to 335-14-7-.16, because it is a very small quantity generator under 335-14-3-.01(4), and elects to withdraw from 335-14-7-.16, must notify the Department using ADEM Form 8700-12 (Notification of Regulated Waste Activity) that it is no longer operating under 335-14-7-.16. A healthcare facility is not required to fill out Schedule A part II.B (Characteristics of Nonlisted Hazardous Waste) and II.C (Listed Hazardous Wastes) of the Notification of Regulated Waste Activity with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Notification of Regulated Waste Activity) for each EPA identification number.

(i) A healthcare facility must submit the Notification of Regulated Waste Activity notifying that it no longer intends to operate subject to 335-14-7-.16 before it begins operating under the conditional exemption of 335-14-3-.01(4).

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) Hazardous waste determination for non-creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in 335-14-2-.03 or is listed in 335-14-2-.04) in order to determine whether the waste is subject to 335-14-7-.16. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under 335-14-7-.16.

(d) Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.

1. A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

2. A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

3. A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

4. A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste

pharmaceuticals prohibited from being combusted because of the dilution prohibition of 40 CFR §268.3(c) [incorporated by reference in 335-14-9-.01(3)] (i.e., metal-bearing waste codes listed in appendix XI of 40 CFR part 268, unless one or more criteria in 40 CFR §268.3(c)(1)through (6)[incorporated by reference at 335-14-9-.01(1)-(6)]are met), or because it is prohibited from being lab packed due to 40 CFR §268.4(c) [incorporated by reference at 335-14-9-.04(3)] (i.e., waste codes listed in appendix XI of 40 CFR part 268), must be accumulated in separate containers and labeled with all applicable EPA hazardous waste numbers (i.e., hazardous waste codes).

(e) Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities

1. A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

2. A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) Land disposal restrictions for non-creditable hazardous waste pharmaceuticals. The non-creditable hazardous waste

pharmaceuticals generated by a healthcare facility are subject to 335-14-9. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with 335-14-9-.01(7), except that it is not required to identify the hazardous waste numbers (i.e., hazardous waste codes) on the land disposal restrictions notification.

(h) Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 335-14-5-.05(3) or 335-14-6-.05(3) may accumulate the rejected non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 calendar days provided the rejected shipment is managed in accordance with 335-14-7-.16(2)(d) and (e). Upon receipt of the rejected shipment, the healthcare facility must:

1. Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

2. Provide the transporter a copy of the manifest;

3. Within 30 calendar days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

4. Within 90 calendar days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of 335-14-7-.16(8)(a).

(i) Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals

1. Biennial reporting by healthcare facilities. Healthcare facilities are not subject to biennial reporting requirements under 335-14-3-.04(2), with respect to non-creditable hazardous waste pharmaceuticals managed under 335-14-7-.16.

2. Exception reporting by healthcare facilities for a missing copy of the manifest.

(i) For shipments from a healthcare facility to a designated facility:

(I) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 calendar days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

I. A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Department; and

II. A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(II) [Reserved]

(ii) For shipments rejected by the designated facility and shipped to an alternate facility.

(I) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 calendar days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

I. A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Department; and

II. A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste

pharmaceuticals and the results of those efforts.

(II) [Reserved]

3. Additional reports. The Department may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.

1. A healthcare facility must keep a copy of each manifest signed in accordance with 335-14-3-.02(4)(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

2. A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

3. A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with 335-14-3-.01(2), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

4. The periods of retention referred to in 335-14-7-.16(2) are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

5. All records must be readily available upon request by an inspector.

(k) Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the applicable requirements of 335-14-7-.16.

(l) Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small

quantity generator. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under 335-14-3-.01(4), without a permit or without having interim status, provided the receiving healthcare facility:

1. Is under the control of the same person (as defined in 335-14-1-.02) as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site ("control" means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in 335-14-1-.01(2) shall not be deemed to "control" such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

2. Is operating under 335-14-7-.16 for the management of its non-creditable hazardous waste pharmaceuticals;

3. Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with 335-14-7-.16; and

4. Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(3) Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) Hazardous waste determination for potentially creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it is listed in 335-14-2-.04 or exhibits a characteristic identified in 335-14-2-.03). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under 335-14-7-.16.

(b) Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under 335-14-3-.01(4), without a permit or

without having interim status, provided the receiving healthcare facility:

1. Is under the control of the same person, as defined in 335-14-1-.01(2), as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

2. Is operating under 335-14-7-.16 for the management of its potentially creditable hazardous waste pharmaceuticals;

3. Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with 335-14-7-.16; and

4. Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) Prohibition. Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) Biennial Reporting by healthcare facilities. Healthcare facilities are not subject to biennial reporting requirements under 335-14-3-.04(2) with respect to potentially creditable hazardous waste pharmaceuticals managed under 335-14-7-.16.

(e) Recordkeeping by healthcare facilities.

1. A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

2. The periods of retention referred to in this rule are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

3. All records must be readily available upon request by an inspector.

(f) Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with 335-14-7-.16.

(4) Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste that are not operating under 335-14-7-.16.

(a) Potentially creditable hazardous waste pharmaceuticals. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off site to another generator, provided:

1. The receiving healthcare facility meets the conditions in 335-14-7-.16(2)(l) and 335-14-7-.16(3)(b), as applicable, or

2. The very small quantity generator healthcare facility meets the conditions in 335-14-3-.01(4)(a)5.(viii) and the receiving large quantity generator meets the conditions in 335-14-3-.01(7)(f).

(c) Long-term care facilities that are very small quantity generators. A long-term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) Long-term care facilities with 20 beds or fewer. A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to 335-14-3-.01(4) for

both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to 335-14-7-.16, except for 335-14-7-.16(5) and 335-14-7-.16(7) and the other optional provisions of 335-14-7-.16(4). The Department has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in 335-14-1-.02(1). A long-term care facility with more than 20 beds that operates as a very small quantity generator under 335-14-3-.01(4) must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by 335-14-1-.02(1).

(5) Prohibition of sewering hazardous waste pharmaceuticals. All healthcare facilities—including very small quantity generators operating under 335-14-3-.01(4) in lieu of 335-14-7-.16—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b).

(6) Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected by an authorized collector.

(a) Conditional exemptions. Provided the conditions of 335-14-7-.16(6)(b) are met, the following are exempt from 335-14-3 through 335-14-11:

1. Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

2. Household waste pharmaceuticals that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) Conditions for exemption. The hazardous waste pharmaceuticals must be:

1. Managed in compliance with the sewer prohibition of 335-14-7-.16(5); and

2. Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

3. Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators; or

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 335-3-3-.05 for new commercial and industrial solid waste incinerators; or

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

(7) Residues of hazardous waste pharmaceuticals in empty containers.

(a) Stock, dispensing and unit-dose containers. A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) Syringes. A syringe is considered empty and the residues are not regulated as hazardous waste under 335-14-7-.16 provided the contents have been removed by fully depressing the plunger of the syringe. At healthcare facilities operating under 335-14-7-.16, if a syringe is not empty, the syringe

must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical 335-14-7-.16 and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) Intravenous (IV) bags. An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient, or if the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in 335-14-2-.01(7). At healthcare facilities operating under 335-14-7-.16, if an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under 335-14-7-.16.

(d) Other containers, including delivery devices. At healthcare facilities operating under 335-14-7-.16, hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under 335-14-7-.16, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in 335-14-2-.01(7)(b)1. or 2. This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

(8) Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

1. The following pre-transport requirements, before transporting or offering for transport off-site:

(i) Packaging. Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) Labeling. Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) Marking.

(I) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D;

(II) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address _____
_____.
Healthcare Facility's or Reverse distributor's EPA Identification Number_____.

Manifest Tracking Number _____.

(III) Lab packs that will be incinerated in compliance with 335-14-9-.04(3) are not required to be marked with EPA Hazardous Waste Number(s) (i.e. hazardous waste codes), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) Placarding. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

2. The manifest requirements of 335-14-3-.02, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700-22 (Uniform Hazardous Waste Manifest).

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word

"PHRM" or "PHARMS" in Item 13 of EPA Form 8700-22 (Uniform Hazardous Waste Manifest). A healthcare facility may also include the applicable EPA hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700-22.

(b) Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 335-14-3-.09.

(c) Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 335-14-3-.09. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

(9) Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) Shipping potentially creditable hazardous waste pharmaceuticals. A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of 335-14-3. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) Delivery confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) Procedures for when delivery confirmation is not received within 35 days. If a healthcare facility or reverse

distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) Exporting potentially creditable hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 335-14-3-.09, except the manifesting requirement of 335-14-3-.09(4), in addition to 335-14-7-.16(9)(a) through (c).

(e) Importing potentially creditable hazardous waste pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into Alabama from outside the United States is subject to 335-14-7-.16(9)(a) through (c) in lieu of 335-14-3-.09. Immediately after the potentially creditable hazardous waste pharmaceuticals enter Alabama from outside the United States, they are subject to all applicable requirements of 335-14-7-.16.

(10) Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors. A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

1. Notification. A reverse distributor must notify the Department, using ADEM Form 8700-12 (Notification of Regulated Waste Activity) or an electronic method used by the Department, that it is a reverse distributor operating under 335-14-7-.16.

(i) A reverse distributor that already has an EPA identification number must notify the Department, using ADEM Form 8700-12 or an electronic method used by the Department, that it is a reverse distributor, as defined in 335-14-1-.02(1), within 60 days of the

effective date of 335-14-7-.16, or within 60 days of becoming subject to 335-14-7-.16.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the Department, using ADEM Form 8700-12 or an electronic method used by the Department, that it is a reverse distributor, as defined in 335-14-1-.02(1), within 60 days of the effective date of 335-14-7-.16, or within 60 days of becoming subject to 335-14-7-.16.

2. Inventory by the reverse distributor. A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (e.g., name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of 335-14-7-.16(10)(a)2. because of other regulatory requirements, such as Alabama Board of Pharmacy rules, the facility is not required to provide a separate inventory pursuant to this rule.

3. Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a potentially creditable hazardous waste pharmaceutical and must be managed in accordance with 335-14-7-.16(10)(b).

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or

interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with 335-14-7-.16(10)(c).

4. Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with 335-14-7-.16(10)(c).

5. Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.

(i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., evaluated hazardous waste pharmaceuticals).

(ii) Aging pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with 335-14-7-.16(10)(a) and the container labeling and management standards in 335-14-7-.16(10)(c)4.(i) through (vi).

6. Security at the reverse distributor facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(I) A 24-hour continuous monitoring surveillance system;

(II) An artificial barrier such as a fence; or

(III) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of 335-14-7-.16(10)(a)6. because of other regulatory requirements, such as Drug Enforcement Administration or Alabama Board of Pharmacy rules, the facility is not required to provide separate security measures pursuant to 335-14-7-.16(10).

7. Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 335-14-3-.14.

8. Closure of a reverse distributor. When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with 335-14-3-.01(7)(a)8.(ii) and (iii).

9. Reporting by a reverse distributor.

(i) Unauthorized waste report. A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the Department within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(I) The EPA identification number, name and address of the healthcare facility (or other entity) that shipped the unauthorized waste, if available;

(II) The date the reverse distributor received the unauthorized waste;

(III) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(IV) A description and the quantity of each unauthorized waste the reverse distributor received;

(V) The method of treatment, storage, or disposal for each unauthorized waste; and

(VI) A brief explanation of why the waste was unauthorized, if known.

(ii) Additional reports. The Department may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

10. Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in 335-14-7-.16(10) are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

(i) A copy of its notification on file for as long as the facility is subject to 335-14-7-.16;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to 335-14-7-.16.

(b) Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in 335-14-7-.16(10)(a), for the management of potentially creditable hazardous waste pharmaceuticals that

are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

1. A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow 335-14-7-.16(10)(c) for evaluated hazardous waste pharmaceuticals.

2. A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow 335-14-7-.16(10)(c) for evaluated hazardous waste pharmaceuticals.

3. A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with 335-14-7-.16(9).

4. Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this rule are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(c) Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of 335-14-7-.16(10)(a), for the management of evaluated hazardous waste pharmaceuticals:

1. Accumulation area at the reverse distributor. A reverse distributor must designate an on-site

accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

2. Inspections of on-site accumulation area. A reverse distributor must inspect its on-site accumulation area at least once every seven calendar days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

3. Personnel training at a reverse distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of 335-14-3-.01(7)(a)7.

4. Labeling and management of containers at on-site accumulation areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, "hazardous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(I) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(II) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(III) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(IV) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(V) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 335-14-9-.01(3)(i.e., metal-bearing waste codes listed in appendix XI of 40 CFR part 268, unless one or more criteria in 40 CFR § 268.3(c)(1) through (6) are met), or because it is prohibited from being lab packed due to 40 CFR § 268.42(c)[incorporated by reference at 335-14-9-.04(3)] (i.e., waste codes listed in appendix IV of 40 CFR part 268), in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

5. Hazardous waste numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.e., hazardous waste codes)), except as provided in 335-14-7-.16(8)(a)1.(iii)(III). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s)(i.e., hazardous waste codes).

6. Shipments. A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in 335-14-7-.16(8)(a) or (b).

7. Procedures for a reverse distributor for managing rejected shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 335-14-5-.05(3) or 335-14-6-.05(3), may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 calendar days in the on-site accumulation area provided the rejected shipment is managed in accordance with 335-14-7-.16(10)(a) and (c). Upon receipt of the rejected shipment, the reverse distributor must:

(i) Sign either:

(I) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(II) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 calendar days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 calendar days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of 335-14-7-.16(8)(a) or (b).

8. Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 335-14-9. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with 335-14-9-.01(7).

9. Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals.

(i) Biennial reporting by a reverse distributor. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the Department by March 1 of each even numbered year in accordance with 335-14-3-.04(2).

(ii) Exception reporting by a reverse distributor for a missing copy of the manifest.

(I) For shipments from a reverse distributor to a designated facility,

I. If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the

transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

II. A reverse distributor must submit an exception report to the Department if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 calendar days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

a. A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

b. A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(II) For shipments rejected by the designated facility and shipped to an alternate facility,

I. A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

II. A reverse distributor must submit an Exception Report to the Department if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the

date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(A) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(B) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

10. Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.

(i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required 335-14-7-.16(10)(c)2. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with 335-14-3-.02(4)(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with 335-14-3-.01(7)(a)7.(iv).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in 335-14-7-.16(10) are extended automatically during the course of any unresolved

enforcement action regarding the regulated activity, or as requested by the Department.

(d) When a reverse distributor must have a permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 335-14-5, 335-14-6, and the permit requirements of 335-14-8, if the reverse distributor:

1. Does not meet the conditions 335-14-7-.16;

2. Accepts manifested hazardous waste from off site; or

3. Treats or disposes of hazardous waste pharmaceuticals on site.

Author: Sonja B. Favors; Brent A. Watson; Jonah L. Harris
Statutory Authority: Code of Ala. 1975, §§22-30-10, 22-30-11, 22-30-12, 22-30-14, 22-30-15, 22-30-16, 22-30-19, 22-30-20.
History: **New Rule**: Published February 28, 2020; effective April 13, 2020. **Amended**: Published November 30, 2022; effective June 12, 2023. **Amended**: Published December 31, 2025; effective February 14, 2026.

335-14-7-.17 Ignitable Spent Refrigerants Recycled for Reuse.

(1) Purpose and applicability

(a) The purpose of 335-17-7-.17 is to reduce emissions of ignitable spent refrigerants to the lowest achievable level by maximizing the recovery and safe recycling for reuse of such refrigerants during the service, repair, and disposal of appliances.

(b) The requirements of 335-17-7-.17 operate in lieu of 335-14-1 through 335-14-9 and apply to lower flammability spent refrigerants, as defined in 335-14-7-.17(2), where the refrigerant exhibits the hazardous waste characteristic of ignitability per 335-14-2-.03(2) and is being recycled for reuse in the United States.

(c) These requirements do not apply to other ignitable spent refrigerants. Ignitable spent refrigerants not subject to 335-17-7-.17 are subject to all applicable requirements of 335-14-1 through 335-14-9 when recovered (i.e., removed from an appliance and stored in an external container) and/or disposed of.

(2) Definitions for 335-17-7-.17. For the purposes of 335-17-7-.17, the following terms have the meanings given below:

(a) Refrigerant has the same meaning as defined in 40 CFR 82.152.

(b) *Ignitable spent refrigerant* is a used refrigerant that cannot be reused without first being processed, and that exhibits the hazardous characteristic of ignitability per 335-14-2-.03(2). Used refrigerants that can be legitimately reused without processing are not spent refrigerant.

(c) *Recycle for reuse,* when referring to an ignitable spent refrigerant, means to process the refrigerant to remove contamination and prepare it to be used again. "Recycle for reuse" does not include recycling that involves burning for energy recovery or use in a manner constituting disposal as defined in 335-14-2-.01(2)(c), or sham recycling as defined in 335-14-2-.01(2)(g).

(d) *Lower flammability spent refrigerant* means a spent refrigerant that is not considered highly flammable. Highly flammable refrigerants include but are not limited to the following chemicals: butane, isobutane, methane, propane, and/or propylene.

(3) Standards for ignitable spent refrigerant recycled for reuse under 335-17-7-.17.

(a) Persons who recover (*i.e.,* remove from an appliance and store in an external container) and/or recycle ignitable spent refrigerants for reuse either for further use in equipment of the same owner, or in compliance with motor vehicle air conditioner (MVAC) standards in 40 CFR part 82, subpart B, or who send recovered refrigerant off-site to be recycled for reuse must:

1. Recover and/or recycle for reuse the ignitable spent refrigerant using equipment that is certified for that type of refrigerant and appliance under 40 CFR §§ 82.36 and/or §§ 82.158;and

2. Not speculatively accumulate the ignitable spent refrigerant per 335-14-1-.02(1)(a).

(b) Persons who receive ignitable spent refrigerants from off-site, and are not a transfer facility that stores the refrigerants for less than ten (10) days before sending the refrigerant to another site to be recycled for reuse, must:

1. If recovering the refrigerant, recover the ignitable spent refrigerant using equipment that is certified for that type of refrigerant and appliance under 40 CFR § 82.36;

2. Meet the applicable emergency preparedness and response requirements of 335-14-2-.13; and

3. Not speculatively accumulate the ignitable spent refrigerant per 335-14-1-.02(1)(a).

(c) Persons receiving ignitable spent refrigerant from off-site to be recycled for reuse under 335-17-7-.17 must:

1. Maintain certification by EPA under 40 CFR §82.164;

2. Meet the applicable emergency preparedness and response requirements of 335-14-2-.13; and

3. Starting with the calendar year beginning January 1, 2029, not speculatively accumulate the ignitable spent refrigerant per 335-14-1-.02(1)(a).

Author: Jonah Harris
Statutory Authority: Code of Alabama 1975, §§ 22-30-11, 22-30-14, 22-30-15 and 22-30-16
History: **New Rule:** Published December 31, 2025; effective February 14, 2026.

335-14-7-A1 **Appendix I - Tier I and Tier II Feed Rate And Emissions Screening Limits For Metals.**

40 CFR, Part 266 Appendix I, of the Environmental Protection Agency Regulations (as published by EPA on February 21, 1991 and amended on July 17, 1991) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference as set forth in 40 CFR, Part 266.

Any provisions of 40 CFR Part 266 Appendix I which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase (at 40 cents a page) and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994 effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A2 **Appendix II - Tier I Feed Rate Screening Limits For Total Chlorine And Chloride.**

40 CFR, Part 266 Appendix II, of the Environmental Protection Agency Regulations (as published by EPA on July 17, 1991) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference as set forth in 40 CFR, Part 266.

Any provisions of 40 CFR Part 266 Appendix II which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994 effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A3 **Appendix III - Tier II Emission Rate Screening Limits For Free Chlorine And Hydrogen Chloride.**

40 CFR, Part 266 Appendix III, of the Environmental Protection Agency Regulations (as published by EPA on July 17, 1991 and amended on July 14, 2006) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference as set forth in 40 CFR, Part 266.

Any provisions of 40 CFR Part 266 Appendix III which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.

History: January 25, 1992. **Amended:** Filed: November 30, 1994 effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A4 Appendix IV - Reference Air Concentrations.

40 CFR, Part 266 Appendix IV, of the Environmental Protection Agency Regulations (as published by EPA on February 21, 1991 and amended on July 17, 1991 and July 14, 2006) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference as set forth in 40 CFR, Part 266.

Any provisions of 40 CFR Part 266 Appendix IV which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A5 Appendix V - Risk Specific Doses.

40 CFR Part 266 Appendix V, of the Environmental Protection Agency Regulations (as published by EPA on February 21, 1991 and amended on July 17, 1991 and July 14, 2006) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference as set forth in 40 CFR, Part 266.

Any provisions of 40 CFR Part 266 Appendix V which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett

Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A6 Appendix VI - Stack Plume Rise.

40 CFR Part 266 Appendix VI, of the Environmental Protection Agency Regulations (as published by EPA on February 21, 1991 and amended on July 17, 1991 and July 14, 2006) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference as set forth in 40 CFR, Part 266.

Any provisions of 40 CFR Part 266 Appendix VI which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A7 Appendix VII - Health Based Limits For Exclusion Of Waste-Derived Residues.

40 CFR Part 266 Appendix VII, of the Environmental Protection Agency Regulations (as published by EPA on February 21, 1991 and amended on July 17, 1991 and November 14, 193) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference.

Any provisions of 40 CFR Part 266 Appendix VII which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A8 Appendix VIII - Potential PICs For Determination Of Exclusion Of Waste-Derived Residues.

40 CFR Part 266 Appendix VIII, of the Environmental Protection Agency Regulations (as published by EPA on September 30, 1999 and amended on November 19, 1999 and July 14, 2006) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference.

Any provisions of 40 CFR Part 266 Appendix VIII which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A9 Appendix IX - Methods Manual For Compliance With The BIF Regulations.

40 CFR Part 266 Appendix IX, of the Environmental Protection Agency Regulations (as published by EPA on July 17, 1991; and amended on August 27, 1991; August 25, 1992; September 30, 1992; June 13, 1997; June 14, 2005; July 14, 2006; and June 25, 2009)

governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference.

Any provisions of 40 CFR Part 266 Appendix IX which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase (at 40 cents a page) and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A10 Appendix X - [Reserved].
Author:
Statutory Authority:
History:

335-14-7-A11 Appendix XI - Lead Bearing Materials That May Be Processed In Exempt Lead Smelters.

40 CFR Part 266 Appendix XI, of the Environmental Protection Agency Regulations (as published by EPA on August 27, 1991) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference.

Any provisions of 40 CFR Part 266 Appendix XI which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase (at 40 cents a page) and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 28, 2006; effective April

4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A12 **Appendix XII - Nickel Or Chromium-Bearing Materials That May Be Processed In Exempt Nickel Chromium Recovery Furnaces.**

40 CFR Part 266 Appendix XII, of the Environmental Protection Agency Regulations (as published by EPA on August 27, 1991) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference.

Any provisions of 40 CFR Part 266 Appendix XII which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: Stephen C. Maurer; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett
Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: January 25, 1992. **Amended:** Filed: November 30, 1994; effective January 5, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.

335-14-7-A13 **Appendix XIII - Mercury Bearing Wastes That May Be Processed In Exempt Mercury Recovery Units.**

40 CFR Part 266 Appendix XIII, of the Environmental Protection Agency Regulations (as published by EPA on September 19, 1994 and amended on July 14, 2006) governing hazardous waste burned in boilers and industrial furnaces, is incorporated herein by reference.

Any provisions of 40 CFR Part 266 Appendix XIII which are inconsistent with other provisions of the ADEM Administrative Code are not incorporated herein by reference.

The materials incorporated by reference are available for purchase and inspection at the Department's offices at 1400 Coliseum Boulevard, Montgomery, Alabama 36110.
Author: C. Lynn Garthright; Amy P. Zachry; Bradley N. Curvin; Vernon H. Crockett

Statutory Authority: Code of Ala. 1975, §§22-30-4, 22-30-6, 22-30-11.
History: New Rule: Filed March 22, 1995; effective April 26, 1995. **New Rule:** Filed February 20, 1998; effective March 27, 1998. **Amended:** Filed March 9, 2001; effective April 13, 2001. **Amended:** Filed February 24, 2005; effective March 31, 2005. **Amended:** Filed February 28, 2006; effective April 4, 2006. **Amended:** Filed February 14, 2017; effective March 31, 2017.